DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

December 3, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20857

Re: In re Korangy Radiology Associates, P.A., et al.
FDA Docket No. 2003H-0432

Dear Sir or Madam:

Enclosed for filing in the above-captioned matter is the original and one copy of Complainant's Post-Hearing Brief on Penalty Amount, along with a Proposed Order. If you have any questions, please call me at (301) 827-5523. Thank you.

Sincerely,

Jennifer E. Dayok
Associate Chief Counsel
for Enforcement

Enclosure

cc w/encl.:

Hon. Daniel J. Davidson, A.L.J.
Henry E. Schwartz, Esq.

2003H-0432

BRF2

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of	)	
KORANGY RADIOLOGY ASSOCIATES, P.A., trading as BALTIMORE IMAGING CENTERS, a corporation,	)	ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PENALTY
and,	)	FDA Docket: 2003H-0432
AMILE A. KORANGY, M.D., an individual.	)	

COMPLAINANT'S POST-HEARING BRIEF ON PENALTY AMOUNT

INTRODUCTION

Complainant, the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), brought this action for administrative civil money penalties (CMP) under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, against Respondents Korangy Radiology Associates, P.A. (KRA), a mammography facility doing business as Baltimore Imaging Centers (BIC), and Amile A. Korangy, M.D., the President and owner of KRA and the Lead Interpreting Physician and Supervision Radiologist of BIC.

On April 2, 2004, Complainant filed a Motion for Partial Summary Decision. On May 27, 2004, the Presiding Officer granted Complainant's Motion, finding that Respondents KRA, trading as BIC, and Dr. Amile Korangy were each liable for 193 violations of the MQSA. The Presiding Officer further ordered that the remainder of the hearing schedule would be "limited to issues relating to the amount of the penalty to be imposed, including any mitigating circumstances, as set forth in 21 C.F.R. § 17.34." Partial Summary Decision, at 10.

On September 20, 2004, this Court held a hearing on mitigating circumstances with respect to the amount of the penalty. September 20, 2004 Hearing Transcript (Hearing Transcript), at 3. While encouraging the parties to settle this matter, the Presiding Officer set a due date of December 3, 2004, for the parties to brief the issue of the amount of penalty. Id. at 7-8, 49.

The parties have attempted to settle this matter, but have been unable to reach agreement on an appropriate CMP. Accordingly, Complainant files this Post-Hearing Brief setting forth its position on penalty amount and answering some defenses that Respondents have raised throughout this proceeding.

ARGUMENT

I. THE APPROPRIATE PENALTY AMOUNT IS $1,158,000.00

When CDRH initiated this action, it sought the maximum amount of CMP provided for by statute due to Respondents' blatant failure to comply with MQSA after receiving several notices from the American College of Radiology (ACR) and CDRH regarding its certification status and the fact that it was unlawful to conduct mammograms without being certified. See Administrative Complaint for Civil Money Penalty, ¶¶ 10-13, 21-23. Despite these warnings, Respondents conducted 192 mammography examinations when it was not certified to do so, and is liable for a total of 386 violations of the MQSA. The statute provides for a maximum penalty of $10,000 per violation, which in this case, is $3.86 million. See 42 U.S.C. § 263b(h)(3).

Respondents claim they are unable to pay the penalty sought in this case. The financial documents provided by Respondents, coupled with information obtained by CDRH independently, paint an unclear picture of Respondents' financial position. Because CDRH believes that Dr. Korangy personally has substantially more assets than he admits and the

corporate Respondent owns property worth over $3,000,000, and given Respondents' obstinate refusal to supply any meaningful documents to support their claim of inability to pay, an appropriate penalty amount for Respondents is $1,158,000 ($579,000 for each Respondent), based on a $3,000 penalty for each of the MSQA violations for which each Respondent is liable.

Throughout this proceeding, Respondents objected to CDRH's discovery attempts to obtain financial information. Specifically, in its First Request for Production of Documents served on January 13, 2004, CDRH requested "[a]ll documents reflecting any or all of the assets, including any ownership interests in any business entity, of each of the Respondents and any of Dr. Amile Korangy's immediate family members," (Request 2) and broadly asked for all documents relating to the annual receipts of Respondents and their affiliates (Request 4).

On January 26, 2004, Respondents filed a Request for Protective Order regarding these discovery requests. On January 30, 2004, the parties filed a Joint Notice and Agreement to Resolve Discovery Dispute (Joint Notice) in which Respondents agreed to respond to certain of CDRH's document requests for financial information no later than sixty days prior to (1) filing any motion, proposed findings of fact, evidence, or any other written document in this proceeding in which all or either of them claim entitlement to a reduction of civil money penalties based on their inability to pay; or (2) the hearing in this proceeding if all or either of them claim, or offer evidence in support of a claim, during such hearing, that they are entitled to a reduction of civil money penalties based on their inability to pay. Joint Notice, at 2-5. The Joint Notice further provided that if Respondents failed to respond to CDRH's financial document requests sixty days prior to filing such document, or the hearing, as described above, Respondents agreed that the Presiding Officer should exclude any evidence of their inability to pay or entitlement to reduction of civil money penalties that is submitted in support of such

written document and/or hearing. Id. On April 7, 2004, the Presiding Officer denied both of Respondents' Requests for Protective Order regarding CDRH's Request for Production of Documents Numbers 2 and 4, ruling that "Respondents' financial data would be relevant to any determination [of penalty amount] under 21 C.F.R. § 17.34. April 7, 2004 Order, ¶¶ 2-3.

Notwithstanding the Presiding Officer's Order regarding the discovery request and Respondents' invocation of the inability to pay defense at the September 20, 2004 hearing, Respondents have never fully responded to CDRH's second and fourth requests for financial information in Complainant's First Request for Production of Documents. Instead, Respondents have provided CDRH with incomplete tax returns and, only after significant delay and much prodding from CDRH, only some small number of the specific documents CDRH requested by letters dated October 1, 2004 and November 8, 2004, and orally on approximately November 22, 2004. See Exhibit G-14 attached hereto.

Accordingly, as it did at the hearing, CDRH again invokes Respondents' agreement in the Joint Notice which permits the Presiding Officer to exclude any evidence of Respondents' inability to pay that was not provided to CDRH by July 21, 2004, sixty days before the hearing. This sanction is appropriate under 21 C.F.R. § 17.35(c) , which permits the Presiding Officer to sanction a party for failing to comply with a discovery order, including prohibiting the party failing to comply "from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought," and to "[s]trike any part of the pleadings and other submissions of the party failing to comply with such request."

In any event, Respondents should not be entitled to a penalty reduction due to their unsupported claim of inability to pay. It is Respondents' burden to prove inability to pay, and they have not done so. In fact, the documents eventually provided in response to CDRH's

repeated requests, as well as the information that CDRH was able to discover from public tax and real property records suggest that Respondents have access to more assets than they have revealed to CDRH or this Court.

For example, Amile Korangy has maintained throughout this proceeding that he owns no real property in his name. See e.g., Hearing Transcript, at 39. While that appears to be true, documents obtained by CDRH paint a picture of a man who, since at least 1996, has taken great measures to avoid holding any property in his own name by, as set forth below, transferring it to his wife and children, into trusts, or into the name of a company that is not readily traceable to him.

Dr. Korangy's activities regarding the ownership of his residence at 13607 Sheepshead Court, Clarksville, MD, 21029, a 7,786 square foot house on 3.38 acres of land (see MD Dept. of Assessments and Taxation Real Property Data Search, attached hereto as Exhibit G-15), demonstrate this point. On December 23, 2003, after a series of transfers of this property beginning in 1996[1] and two months after this action was filed, Dr. Korangy transferred this home out of his name into a trust for which his wife, Parvane S. Kornagy, is trustee. See Exhibit G-16, at 5. Although Dr. Korangy claims he does not own this residence, it is quite clear from the pattern of transfers that he has full control over the home. Moreover, given that his wife's W-2

[1] Since 1996, there have been several curious transfers of ownership for this property among Amile Korangy, his wife, and various trusts. See Property Transfer Records for Howard County, MD, Ex. G-16. On March 22, 1996, the property transferred from Amile A. Korangy to The Korangy Family Revocable Trust. On December 9, 1998, the property transferred from The Korangy Family Revocable Trust to Amile A. and Parvane S. Korangy, tenants by the entirety. That same day, Amile A. Korangy transferred the property to a trust with himself as the trustee. Then, on December 23, 2003, as trustee, Amile A. Korangy transferred the property back to himself and Parvane S. Korangy as tenants by the entirety, and then transferred the property to a trust with Parvane S. Korangy as trustee. The two transfers on December 23, 2003 occurred two months after the filing of this action and removed Amile Korangy's name from the property entirely.

Wage and Tax Statement from 2003 records her wages, tips, or other compensation as just over $16,500, the available evidence strongly suggests that Dr. Korangy, not his wife, is responsible for the payments and maintenance costs of this home. W-2 Wage and Tax Statement for Parvane Korangy, 2003, attached hereto as Exhibit G-17. As of January 1, 2002, this property was valued for tax purposes at $987,580. See Exhibit G-15. The market value of this home is most likely significantly more than the tax assessment value, based on the limited evidence the government could gather through the public records, probably in the $1.2 to $1.5 million range.[2]

Dr. Korangy's pattern of making sure that his assets are held in another name is also reflected in his car registration. At the September 20, 2004 hearing, Dr. Korangy stated that he does not have a car and that he did not have a car in his name. Hearing Transcript, at 40-41. When CDRH requested titles to vehicles or other documents reflecting ownership of vehicles by Respondents, Respondents first gave CDRH Purchase Orders and Bills of Sale for a used 2000 Toyota Corolla registered in the name of BIC and a used 1998 Volkswagen Jetta GLX registered in the name of KRA. See Used Vehicle Purchase Orders and Bills of Sale, attached hereto as Exhibit G-19. Only after being asked by Complainant to confirm that the Corolla and Jetta were the only vehicles owned by KRA and/or Amile Korangy did Respondents produce evidence of the purchase of two additional, and far more expensive cars: a 2003 Mercedes Benz E500 purchased for $72,525.60 on April 28, 2003, in the name of BIC and a GMC Yukon XL purchased for $49,085.20 on June 21, 2003, in the name of "Baltimore Imagine (sic) Center, Michael Shahram Korangy." See Mercedes-Benz Credit Retail Installment Contract and Retail

[2] A neighboring house at 13600 Sheepshead Ct., Clarksville, MD, is currently under contract and was listed for $1,299,000. A house generally comparable to Dr. Korangy's on a neighboring street is under contract for $1.5 million. See Metropolitan Regional Information Systems, Inc. Reports, Exhibit G-18 attached hereto.

Instalment (sic) Sale Contract from Performance Pontiac-Ellicott City, attached hereto as Exhibit G-20. Thus, in 2003 alone, Dr. Korangy purchased two cars worth over $120,000, although neither is registered in his name.

Additionally, on December 1, 1999 and January 24, 2000, Dr. Korangy transferred real property that he owns in Indian River County, Florida, out of his name into a company called Paskor, LLC (Paskor). See Property Transfer Records for Indian River County, FL, attached hereto as Exhibit G-21. This company was registered with the Florida Department of State, Division of Corporations on December 6, 1999, and the registered mailing address for the company is 13607 Sheeps Head Court, Clarksville, MD 21029 — Dr. Korangy's residence. See Florida Department of State, Division of Corporations, Corporations Online Public Inquiry, attached hereto as Exhibit G-22. In the Florida filing, Dr. Korangy is a listed as the MGRM (Managing Member) of Paskor. Id. The property owned by Paskor, which consists of multiple lots along Highway AIA in Vero Beach, was assessed in 2004 at $249,260. See Exhibit G-21 and Indian River County Online, History of Parcel owned by Paskor, attached hereto as Exhibit G-23. On November 1, 2004, the TCPalm website reported that "Paskor LLC of Clarksville, Md., wants to develop 3.7 acres of oak-covered woodland west of State Road A1A and south of Seaview Drive" in Indian River County. See TCPalm: County planners deny change in land density, attached hereto as Exhibit G-24. Dr. Korangy has never given CDRH any documents regarding his assets in Paskor, and his involvement in Paskor is further evidence that he has additional undisclosed assets from which, contrary to his claims, he is able to pay a CMP in this case.[3]

[3] When Complainant's counsel questioned Respondents' counsel about Paskor on November 29, 2004, Respondents' counsel relayed from Dr. Korangy that he sold the property in Indian River County, FL, in 1999 to a group of people including two of his children. He stated that he

Dr. Korangy's 2003 personal tax return shows dividends in the amount of $5,473, from Legg Mason Wood Walker, Inc. See 2003 1040 for Amile A. and Parvane S. Korangy, 2003, Exhibit G-25 attached hereto. When CDRH questioned Dr. Korangy about the underlying investment giving rise to these dividends, Dr. Korangy, consistent with his pattern of denying ownership of assets, answered that "the $5,000 dividend by Legg Mason belongs to my wife's account and does not belong to me." See Letter to Mr. Schwartz from Amile A. Korangy, faxed on November 24, 2004, attached hereto as Exhibit G-26. Again, Dr. Korangy failed to provide CDRH with any documentation of this investment.

Dr. Korangy and KRA own condominiums at 724 Maiden Choice Lane, Baltimore, MD, 21228, Units C1B, C1C, and C1D, which were assessed for tax purposes as of January 1, 2003, at $114,500, $209,100, and $137,900, respectively. See MD Dept. of Assessments and Taxation, Real Property Data Search, attached hereto as Exhibit G-27. Through his company Pikesville Properties, LLC, Dr. Korangy also owns property at 6609 Reisterstown Road, Baltimore, MD, 21215, that he bought for $1,000,000 on January 22, 2002. See Property Transfer Record for Baltimore City, MD, attached hereto as Exhibit G-28. And on July 30, 2004, Dr. Korangy registered another radiology facility in Frederick, Maryland, called Frederick Imaging Center, LLC. See MD Dept. of Assessments and Taxation, attached hereto as Exhibit G-29. In total, Dr. Korangy operates at least six radiology facilities, three of which perform mammography examinations. Hearing Transcript, at 38.

KRA's 2003 tax return, which shows a net loss of approximately $380,000, states that the company began tax year 2003 with buildings and other depreciable assets worth $1,294,646 and

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received some money from the sale, which he put into his business, but that he had no ownership in Paskor. Dr. Korangy's denial of ownership of a company for which he is the Managing Member is consistent with his denial of owning his home and his cars.

ended that tax year with buildings and other depreciable assets worth $2,585,707. See 2003 1120S for KRA, attached hereto as Exhibit G-30. Thus, KRA purchased or acquired another $1.2 million worth of buildings and other appreciable assets in the 2003 tax year, yet Respondents have not provided CDRH any information about those assets.

Thus, it is quite clear that Dr. Korangy has engaged in creative asset management – including property transfers. Based on the limited number of records provided to CDRH or available publicly, he and KRA likely own real estate worth over $4 million, including Dr. Korangy's residence and KRA's properties. Although the tax returns provided by Respondents would seem to suggest that Dr. Korangy and his wife make only $132,593, see Exhibit G-25, and that KRA is operating at a loss, see Exhibit G-30, it is quite clear that Respondents have numerous assets available to them to pay a significant CMP in this case. Indeed, Respondents' activities in hiding assets from CDRH constitute an aggravating factor that the Presiding Officer should consider under 21 C.F.R. § 17.34(a) when determining an appropriate CMP in this matter.

Because a CMP is a remedial fine rather than a punishment, as discussed in Section II infra., and it is not CDRH's intention to bankrupt Respondents, CDRH believes that an appropriate CMP would be $1,158,000, which amounts to $3,000 per violation of the MQSA.

II. THE CIVIL MONEY PENALTY AMOUNT DOES NOT VIOLATE THE EIGHTH AMENDMENT'S PROHIBITION AGAINST EXCESSIVE FINES

Respondents' lawyer has stated that he believes the CMP sought in this matter is "grossly disproportionate to the offenses charged and, therefore, violate[s] the Eighth Amendment to the Constitution of the United States." Hearing Transcript, at 44-45. The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U.S. Const. amend. VIII.

The Supreme Court has explained that, at the time the Constitution was adopted, "the word 'fine' was understood to mean a payment to a sovereign as punishment for some offense." Browning-Ferris Industries of Vt. v. Kelco Disposal, Inc., 492 U.S. 257, 265 (1989). Accordingly the purpose of the Excessive Fines Clause is to limit "the government's power to extract payment, whether in case or kind, as punishment for some offense." United States v. Bajakajian, 524 U.S. 321, 325 (1998) (quoting Austin v. United States, 509 U.S. 602, 609-110 (1993)).

The CMP sanction in the MQSA, like the CMP sanctions the Federal Food, Drug, and Cosmetic Act, is not intended to be punitive. Rather, it is a remedial sanction "intended to assist the agency in safeguarding the regulatory system." See Civil Money Penalties: Biologics, Drugs, and Medical Devices, Final Rule, 60 Fed. Reg. 38612, 38613. As the agency has explained about the CMPs sanction available under the Safe Medical Devices Act of 1990 (SMDA), CMP authority is intended to take the profit out of non-compliance: "CMP is considered to be a remedial action, not punitive. This means it is designated to influence future conduct of the affected firm and/or other firms that are similarly situated, either directly, by affecting current violative conduct, or indirectly, by serving to deter future violative conduct." See Guidance for FDA Staff, Civil Money Penalty Policy, SMDA Civil Money Penalty Decision Tree, June 8, 1999, found at www.fda.gov/cdrh/comp/penalty.pdf, at 1.

Because the CMP sanction under the MQSA serves the same remedial purpose as other CMPs available in statutes enforced by FDA, they are not "fines" within the meaning of the Excessive Fines Clause of the Eighth Amendment. Accordingly, Respondents' argument that the CMPs in this case violate the Eighth Amendment must fail.

Even if the Excessive Fines Clause were applicable to CMPs assessed under the MQSA, the amount sought in this matter does not exceed the statutory maximum allowed and is not grossly excessive. The Supreme Court has acknowledged that "judgments about the appropriate punishment for an offense belong in the first instance to the legislature." Bajakajian, 524 U.S. at 336 (citations omitted). The MQSA permits a CMP of up to $10,000 per violation, and the initial penalty sought in this case does not deviate from that statutory maximum. "No matter how excessive (in lay terms) an administrative fine may appear, if the fine does not exceed the limits prescribed by the statute authorizing it, the fine does not violate the *Eighth* Amendment." Cox v. FEC, 2004 U.S. Dist. LEXIS 6939, *44 (Jan. 2004) (quoting Newell Recycling Co. v. EPA, 231 F.3d 204, 210 (5th Cir. 2000)).

In order to prevail on their claim that the CMPs violate the Excessive Fines Clause, Respondents bear the burden to show "that the fine is unconstitutionally excessive so as to justify the extraordinary step of overruling the legislature in this instance." Id. at *47. They cannot meet that burden here.

In deriving a constitutional excessiveness standard, the Supreme Court in Bajakajian, 524 U.S. at 336, adopted the "gross proportionality standard" from Solem v. Helm, 463 U.S. 277, 288 (1983), which dealt with the Cruel and Usual Punishments Clause of the Eighth Amendment. These cases found fines to be unconstitutional if the amount of the fine was grossly disproportional to the gravity of the offense. Bajakajian, 524 U.S. at 337.

As the record reflects, Respondents had been warned by FDA and ACR that their certification was about to expire and that they were not to continue to perform mammograms without a certification. Nevertheless, Respondents failed to re-certify and continued to perform mammograms.

Congress passed the MQSA to ensure that mammography performed throughout the country is safe and reliable to assure early breast cancer detection, which can lead to early treatment and increased chances of survival. Certification means a mammography facility has been certified either by FDA or an approved State certification agency as capable of providing quality mammography. Facilities that are certified have either completed a rigorous review of the standards (called accreditation) or are undergoing that process. To be certified, a facility must: have specific mammography equipment that is periodically surveyed; employ specially trained personnel to administer tests and interpret data; and have a quality assurance program. In addition, each facility must have a system for following up on mammograms that reveal problems, and for obtaining biopsy results.

Respondents failed to re-certify their mammography facility and tested 192 patients while uncertified. This offense is grave, because it put nearly 200 women a risk of having mammograms that would not detect breast cancer. A lack of reliable early screening puts at risk those who rely on the testing, because they may have a false sense of security or fail to obtain treatment at a stage at which the cancer is most effectively treated. The fine sought for these violations does not exceed that allowed by statute and, therefore, cannot be said to be grossly disproportionate to the serious nature of Respondents' behavior.

III. CDRH MET ITS BURDEN OF PROOF THAT THE CMP IS APPROPRIATE

During the September 20, 2004 hearing, Respondents' counsel stated that CDRH did not prove the appropriateness of penalty by a preponderance of the evidence, as required by 21 C.F.R. § 17.33. Hearing Transcript, at 44. Pursuant to 21 C.F.R. § 17.33(b), CDRH "must prove respondent's liability and the appropriateness of the penalty under the applicable statute by the preponderance of the evidence." The "preponderance of evidence" standard of proof in a civil

case is defined as "evidence which is of greater weight or more convincing than the evidence which is offered in opposition to it; that is, evidence which as a whole shows that the fact sought to be proved is more probable than not." Black's Law Dictionary, 6th ed. (1990), at 1182.

In finding Respondents liable for violations of the MQSA, this Court has already determined that the evidence as a whole shows that it is more probable than not that Respondents failed to obtain a certificate to conduct mammography examinations, as required by 42 U.S.C. § 263b(b) and conducted, or aided and abetting in the conducting of, 192 mammography examinations while the facility was uncertified, in violation of 42 U.S.C. § 263b(b)(1). Partial Summary Decision, at 9-10.

The preponderance of the evidence also shows that a significant CMP is appropriate in this case. As set forth above, as well as in previous pleadings filed with this Court, Respondents' conduct, committed over a period of two months, put almost 200 patients at risk that their mammograms would not detect breast cancer at a stage where treatment would be most effective. In addition, CDRH has presented ample evidence that Respondents committed these offenses with full knowledge that their certificate had expired and that they could not lawfully conduct mammograms without a valid certificate. See Complainant's Proposed Findings of Fact and Requests for Cross-Examination, at 3-8. This evidence, along with Congress' finding that each violation of the MQSA warrants a penalty up to $10,000, supports the penalty sought by CDRH.

IV. CMP IS AN APPROPRIATE SANCTION UNDER THE MQSA

Respondents' attorney also argued that the Secretary failed to develop procedures with respect to when and how the CMP sanction was to be imposed, as required by 42 U.S.C. § 263(h)(4), and that purported failure makes the sanction of CMP inappropriate in any amount. Hearing Transcript, at 44. His premise is incorrect however, and his argument must fail.

Title 42, United States Code, Section 263(h)(4) states that:

> [t]he Secretary shall develop and implement procedures with respect to when and how each of the sanctions is to be imposed under paragraphs (1) though (3). Such procedures shall provide for notice to the owner or operator of the facility and a reasonable opportunity for the owner or operator of the facility to respond to the proposed sanctions and appropriate procedures for appealing determinations relating to the imposition of sanctions.

In FDA's Compliance Program Guidance (CPG) Manual, the program addressing mammography facility inspections articulates procedures for the CMP sanction. CPG 7382.014, September 30, 1999, attached hereto as Exhibit G-31, at Part III, Pages 11-15. The CPG makes clear that once-certified facilities whose certificate expires before they seek reaccreditation, among other facilities, "should be considered for regulatory action by the agency. Any facility can be assessed with civil money penalties or enjoined from operating if it is found to be operating while uncertified." Id. at 12. The CPG explains what evidence must be obtained to support a CMP action, and requires prior notice before the considering the CMP sanction:

> When evidence confirms that an uncertified facility is performing mammography, consideration should be given to the extent of the illegal operation and if there is evidence that the facility has quality problems. Evidence of quality problems might be that the facility was operating after being denied accreditation. Facilities that have performed mammography uncertified or continue to perform mammography uncertified may be subject to Civil Money Penalties or an injunction. The decision as to whether a facility should receive a Warning Letter or Civil Money Penalties would depend on the severity of the situation found. Prior notice should be established before considering Civil Money Penalties. Factors affecting severity could include the number of patients that were examined while uncertified, whether the facility knew that it was performing mammography uncertified (i.e., was it clear from correspondence that the facility received that they were no longer certified), ... If documentation establishing illegal operation is adequate to support a case and prior notice has been established, the District should consider a recommendation for Civil Money Penalties.

Id. at 14-15.

The CPG contains procedures for when CDRH could pursue a Directed Plan of Correction (DPC) or Suspension under the MQSA, and explains that, under section 354(h)(3) of the MQSA, 42 U.S.C. § 263b(h)(3)[4], FDA must develop and implement procedures that provide notice to the facility owner or operator, a reasonable opportunity for the owner or operator to respond to the proposed sanction, and appropriate procedures for appealing determinations relating to the imposition of sanction. Id. at Part V, Page 4. The CPG then notes that "[s]imilar procedures will be used regarding the use of CMP. FDA has specific regulations for CMP procedures at 21 C.F.R. Part 17." Id. at Part V, Pages 3-4.

FDA's regulations in 21 C.F.R. Part 17 "set[ ] forth practices and procedures for hearings concerning the administrative imposition of civil money penalties by FDA." 21 C.F.R. § 17.1. The regulation specifies that CMPs under "Section 354(h)(2) of the [Public Health Service] Act, as amended by the [MQSA], authorizing civil money penalties for failure to obtain a certificate, failure to comply with established standards, among other things" are governed by the Part 17 procedures. 21 C.F.R. § 17.1(d).

The regulations in Part 17 are explicit, declaring what information must appear in a CMP complaint, explaining how the hearing will be conducted and how the amount of penalties and assessments are determined, and providing for both interlocutory and final appeals. See e.g., 21 C.F.R. §§ 17.5, 17.18, 17.34. These regulations and FDA's CPG regarding mammography inspections are the procedures required under 42 U.S.C. § 263(h)(4). Accordingly, Respondents' argument that the Secretary failed to devise procedures as required under the MQSA is incorrect, and CMP is an appropriate sanction under the MQSA.

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[4] This CPG was transmitted to FDA field personnel on May 12, 1998. The MQSA was amended by the Mammography Quality Standards Reauthorization Act of 1998 (MQSRA), at

CONCLUSION

For the foregoing reasons, CDRH respectfully requests that this Court enter an Order assessing CMPs against Respondents in the amount of $1,158,000 ($579,000 per Respondent) comprised of $3,000 for each of the 193 violations of the MQSA for which this Court found each Respondent liable.

Respectfully submitted,

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which time a section on patient information was added at 42 U.S.C. § 263b(h)(2), which moved (h)(3) to the current (h)(4).

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of	)	
KORANGY RADIOLOGY ASSOCIATES, P.A., trading as BALTIMORE IMAGING CENTERS, a corporation,	)	ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PENALTY
and,	)	FDA Docket: 2003H-0432
AMILE A. KORANGY, M.D., an individual.	)	

PROPOSED ORDER

After considering all of the evidence in the record, including the rebuttal evidence submitted by Complainant CDRH in its Post-Hearing Brief on Penalty Amount, which evidence is hereby admitted into the record, as well as the arguments of the parties regarding the penalty amount,

It is ORDERED that Respondent Amile A. Korangy, M.D., pay a total civil money penalty of $579,000, comprised of $3,000 for each of the 193 violations of the Mammography Quality Standards Act for which this Court found Respondent liable in its Order dated May 27, 2004;

It is further ORDERED that Respondent Korangy Radiology Associates, P.A., trading as Baltimore Imaging Centers, pay a total civil money penalty of $579,000, comprised of $3,000 for each of the 193 violations of the Mammography Quality Standards Act for which this Court found Respondent liable in its Order dated May 27, 2004.

Dated this _____day of December, 2004

Daniel J. Davidson
Administrative Law Judge